REMARKS

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks herewith, which are believed to place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 9-21, 29-31, and 55-61 are currently pending. By this paper claims 1, 12, 13, 55, and 56 have been amended, and new claims 57-61 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added. New claims 57-61 recite the subject matter of claims 1, 12, 13, 55 and 56 but without the recitation of homologous sequences.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claim and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

i. Braig *et al.* in view of Holland *et al.*

In the present Office Action the Examiner maintains his previous rejection of claims 1, 9-21, 29-31, and 55-56 under 35 U.S.C. § 103(a) as being unpatentable over Braig *et al.* in view of Holland *et al.* This rejection is respectfully traversed.

The Examiner rejects the arguments made previously in response to this rejection, and re-asserts that it would have been obvious to identify the claimed fragments of GroEL that have chaperone activity. Applicants respectfully disagree. In the discussion section of Braig *et al.* it is specifically stated that "the main function of GroEL is to provide an interactive surface". Clearly, disruption of such an interaction surface, for example by isolating fragments of it, is discouraged by Braig *et al.* Moreover, as detailed in the introduction to the present application, attempts to produce monomers GroEL in the past have either resulted in the formation of non-functional proteins, or, where some function has been reported, that function has been attributed

to re-association of GroEL into multimers. Thus, at the time of the present invention, oe of skill in the art would not have reason to expect that monomeric GroEL fragments would be active, and there would have been no motivation to disrupt the interaction surface of GroEL to make fragments.

The combination of Braig *et al.* with Holland *et al.* does not cure this deficiency. Holland *et al.*, teaches a process of making secreted recombinant fusion polypeptides including polypeptides of bacterial origin. As described above, Braig *et al.* fails to teach or suggest the claimed fragments, and indeed teaches away from such fragments being functional. Therefore, the claimed fragments would not have been obvious to one of skill in the art, regardless of whether those fragments were to be produced as secreted recombinant fusion polypeptides or to be produced by some other method

ii. Amino acid residues 262 and 267

In response to the previous Office Action, Applicants argued that Braig *et al.* does not disclose a sequence for GroEL where amino acid residue 262 is not an alanine or where amino acid residue 267 is not an isoleucine. In the present Office Action, the Examiner points out the homologues encompassed in the instant claims are not limited to having amino acid residue 262 that is not an alanine or amino acid residue 267 that is not an isoleucine. By this paper claims 1, 12, 13, 55 and 56 are amended to clarify that the limitation regarding amino acid positions 262 and 267 also applies to the recited homologues. In addition, new claims 57-61 which do not recite homologues, have been added.

iii. Labigne *et al.*

The Office Action rejects claims 1, 9-21, 29-31, and 55-56 under 35 U.S.C. § 103(a) as being unpatentable over Labigne *et al.* This rejection is respectfully traversed.

Labigne discloses fragments of chaperonins for use as immunogens. Labigne *et al.* is not concerned with refolding of proteins. The Office Action argues that the fragments of the present invention are encompassed by those disclosed by Labigne *et al.* because it would have been obvious to utilize only those fragments taught by Labigne *et al.* that have biological activity in therapeutic compositions and or kits. Applicants disagree with this line of argument.

Firstly, as described above in relation to Braig *et al.*, the person skilled in the art would not have expected the fragments of the present invention to be functional chaperone polypeptides having refolding activity. Labigne *et al.* does not teach or suggest anything about refolding

activity, but is instead concerned with fragments that are immunogenic. Fragments suitable for use as immunogens need not have biological activity. On the contrary, biological activity is an undesirable feature for immunogens and is strongly contra-indicated in vaccines – immunogens should stimulate the desrired immunological response but not have other biological effects such as affecting protein folding.

Secondly, Labigne *et al.* fails to teach or suggest GroEL sequences where amino acid residue 262 is not an alanine or where amino acid residue 267 is not an isoleucine, as recited in the claims of the present application.

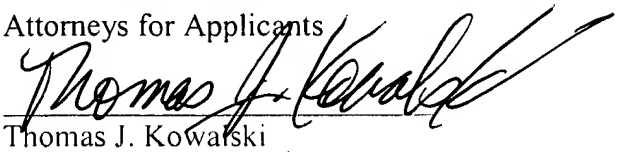
Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

In view of the amendments and remarks herein, Applicants have addressed and overcome all rejections of the application set forth in the Office Action, and the present application is in condition for allowance. Early and favorable reconsideration and withdrawal of the rejections of the application as set forth in the Office Action, and, prompt issuance of a Notice of Allowance, are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: 

Thomas J. Kowalski
Reg. No. 32,147
Tel 212-588-0800
Fax 212-588-0500